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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,473	08/28/2003	Urs Kipfer	14500.01	6136
7590 10/05/2004				
David E. Bruhn DORSEY & WHITNEY LLP Intellectual Property Department 50 South Sixth Street, Suite 1500 Minneapolis, MN 55402-1498			EXAMINER WILLIAMS, CATHERINE SERKE	
			ART UNIT 3763	PAPER NUMBER
DATE MAILED: 10/05/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,473

Applicant(s)

KIPFER, URS

Examiner

Catherine S. Williams

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “controller”, “an occlusion or leakage sensor”, “a dispensing mechanism”, “a driven element” and “a drive device” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled “Replacement Sheet” in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Claim Objections

Claim 7 is objected to because of the following informalities: "the pre-programmed amount" should read --a pre-programmed amount--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3, the word "means" is preceded by the word(s) "display" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. Applicant has in effect failed to particularly point out and distinctly claim the

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invention as required by the second paragraph of section 112.” In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

The corresponding structure (or material or acts) of a means (or step)-plus-function limitation must be disclosed in the specification itself in a way that one skilled in the art will understand what structure (or material or acts) will perform the recited function. See Atmel Corp. v. Information Storage Devices, Inc., 198 F.3d 1374, 1381, 53 USPQ2d 1225, 1230 (Fed. Cir. 1999).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2,7-8,10-11 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Haerten et al (USPN 4,077,405).

“The embodiment according to FIG. 1 is designated specifically for controlling the flow, the feeding conduit comprises a flow-limiting device or throttle 19 disposed in said feeding conduit between valve 8 and catheter 7. Said flow-limiting device consists, in the present case, of a capillary tube composed of glass or plastic material and having a length of approximately 10 mm, and an inner diameter of about from 5 to 50 .mu.m. The inside diameter, and thus the flow can be adjusted individually by twisting said tube around its longitudinal axis. The arrangement

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furthermore comprises an energy supply source 20 for switch pulse transmitter 9 (which, source 20, for example, may be a battery, rechargeable accumulator, a PU capsule, or a bio-fuel cell). Finally, reference number 21 designates a temperature or pressure sensor which senses a change in temperature, for example, caused by fever, or any change of the effective pressure in overpressure generator 2 caused by a temperature change, and by feeding a signal to pulse transmitter 9 counteracts any change of the flow of medication by adjusting the switching period of the valve inversely proportional to the change in pressure.” See Detailed Description, paragraph 7. The active substance is insulin.

Claims 1-3,7-8,10-11 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw (USPN 4,010,749).

“In operation, the two heat sensors 17 and 19 are located within the heated region of the patient's skin surface and normally produce substantial equal output signals. However, in the event the liquid being infused undesirably accumulates about the needle 21 in a perivascular region rather than being properly administered into a blood vessel, the liquid accumulation will alter the skin temperature in the region of sensor 19. The output signal due to this change in temperature may be compared in amplifier 36 with the output signal of sensor 17 or with the output of reference supply 37 of the sensing circuit 39. The reference signal from supply 37 or the output signal from sensor 17 will thus be representative of elevated skin temperature (i.e., about 35.degree. C.-39.degree. C.), independent of the patient's condition. If the amplified difference signal on line 41 exceeds a selected value as determined by threshold detector 43, an output signal is produced on line 45 which may actuate an alarm 47 or actuate the flow controller

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25 to terminate further liquid infusion, or both.” See Detailed Description, paragraph 4. Display means is considered inherent in order to read the temperature

Claims 1-3 and 9-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Cartledge (USPN 6,328,712).

“The adjustable rapid infusion system comprises a reservoir that can have a capacity that can exceed several liters for holding a supply of physiologic fluid, the inventive infusion pump selected from known pumps, including, but not limited to the group consisting of gear pumps, turbine pumps, screw pumps, diaphragm pumps, centrifugal pumps, centripetal pumps, piston pumps, peristaltic pumps, roller head occlusive pumps, nonocclusive centrifugal pumps and the like; optional portions such as a flow rate feed back means that can adjust the fluid flow rate responsive to inputs, a temperature controlling means; a filter to remove any occlusive material from the physiologic fluid; a sensor for detecting the presence of air, tube occlusion, or increased pressure in the physiologic fluid in conjunction with means for cutting off the flow in the conduit in response to a detected predetermined quantity of air, presence of an occlusion or increased pressure. The pump advantageously is infinitely adjustable and can provide fluid flow rates from about 40 cc/hour to about 2.5 l/minute. Optionally, the present rapid infusion system may employ two or more pumps depending upon the amount of fluid needed.” See Detailed Description, paragraph 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw. Shaw meets the claim limitations as described above but fails to include an acoustic alarm, a vibratory alarm or a graphic alarm. However, Shaw does disclose the use of an alarm. See above.

At the time of the invention, it would have been obvious to incorporate any one of the above alarms into the system of Shaw. Shaw discloses the general use of an alarm; therefore, the motivation for incorporating the alarm is provided by Shaw and an incorporation is proper. Additionally, the motivation for incorporating any of the above alarms would be to have different alarm mechanisms to alert individuals that are hearing or sight impaired.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *C.S.W.*
September 30, 2004



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